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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/903,582	07/13/2001	Song Hu	CL001274	6381

25748 7590 07/29/2005

CELERA GENOMICS
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EXAMINER	
RAMIREZ, DELIA M	

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 07/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/903,582	HU ET AL.	
	Examiner	Art Unit	
	Delia M. Ramirez	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-23 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-23 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

Claims 1-23 are pending.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-2, 20-21, drawn to an isolated polypeptide, classified in class 530, subclass 350.

II. Claim 3, drawn to an isolated antibody, classified in class 530, subclass 387.1.

III. Claims 4-6, 8-11, 22-23, drawn to an isolated polynucleotide, a gene chip comprising the polynucleotide, vectors comprising the polynucleotide, host cells comprising the vector, and a method to recombinantly produce the polypeptide encoded by the polynucleotide, classified in class 536, subclass 23.1.

IV. Claim 7, drawn to a transgenic non-human animal comprising a polynucleotide, classified in class 800, subclass 13.

V. Claim 12, drawn to a method for detecting the presence of a polypeptide, classified in class 435, subclass 7.1.

VI. Claim 13, drawn to a method for detecting the presence of a nucleic acid, classified in class 435, subclass 6.

VII. Claims 14-15, drawn to a method for identifying a modulator of a polypeptide, classified in class 436, subclass 86.

VIII. Claim 16, drawn to a method for identifying an agent that binds to a polypeptide, classified in class 435, subclass 7.1.

IX. Claim 17, drawn to a pharmaceutical composition comprising an undefined agent which binds to a polypeptide, classified in class 514, subclass 789.

X. Claim 18, drawn to a method for treating a disease or condition mediated by a human secreted protein, classified in class 514, subclass 789.

XI. Claim 19, drawn to a method for identifying a modulator of the expression of a polypeptide, classified in class 435, subclass 6.

The inventions are distinct, each from the other because of the following reasons:

2. Groups I-IV and IX each comprise a chemically unrelated structure capable of separate manufacture, use, and effect. The polynucleotide in Group III comprises purine and pyrimidine units, the

transgenic non-human animal in Group IV is a multicellular organism whereas the proteins of Group I and II comprise amino acids and have unrelated amino acid sequences. Thus, they are structurally and chemically distinct products. The pharmaceutical composition of Group IX comprises an undefined agent which can be chemical or a biological compound. The polynucleotide has other uses besides encoding the protein of Group I or being introduced in the transgenic non-human animal of Group IV, such as a hybridization probe or in gene therapy. The transgenic animal of Group IV can have other uses such as in vivo testing besides manufacturing the protein of Group I. The protein of Group I can be used in materially different methods other than to make the antibody of Group II, such as in therapeutic or diagnostic methods (e.g. in screening). Further, the protein of Group I can be prepared by processes which are materially different from recombinant polynucleotide expression of Group III or expression in the transgenic non-human animal of Group IV, such as by chemical synthesis, or by isolation and purification from natural sources. The antibody of Group II is neither encoded by the polynucleotide of Group III nor is made by the transgenic non-human animal of Group IV. While one could argue that the antibody of Group II is related to the pharmaceutical composition of Group IX by virtue of being an agent capable of binding the polypeptide of Group I, it is noted that the agent in the pharmaceutical composition of Group IX can be chemically and functionally unrelated to immunoglogulins, therefore the antibody of Group II is not required for the composition of Group IX.

3. The polypeptide of Group I and the methods of Groups V, VII, VIII and XI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide of Group I can be used in the methods of Groups V, VII, VIII and XI as well as in the production of the antibody of Group II.

4. The polynucleotide of Group III and the method of Group VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polynucleotide of Group III can be used in the method of Group VI as well as in the recombinant production of the polypeptide of Group I.

5. The pharmaceutical composition of Group IX and the method of Group X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the pharmaceutical composition of Group IX can be used in the method of Group X as well as an affinity reagent for the purification of the polypeptide of Group I.

6. The antibody of Group II and the methods of Groups V and X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody of Group II can be used in the methods of Groups V and X as well as in the purification of the polypeptide of Group I.

7. The polypeptide of Group I and the methods of Groups VI and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the polypeptide of Group I is neither used nor made by the methods of Groups VI or X.

8. The polynucleotide of Group III and the methods of Groups V, VII, VIII, X, XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they

have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the polynucleotide of Group III is neither used nor made by the methods of Groups V, VII, VIII, X, or XI.

9. The antibody of Group II and the methods of Groups VI, VII, VIII, and XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the antibody of Group II is neither used nor made by the methods of Groups VI, VII, VIII, or XI.

10. The pharmaceutical composition of Group IX and the methods of Groups V-VIII, and XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the pharmaceutical composition of Group IX is neither made nor use by the methods of Groups V-VIII or XI.

11. The transgenic non-human animal of Group IV and the methods of Groups V-VIII, X, and XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the transgenic animal of Group IV is neither made nor use by the methods of Groups V-VIII, X, or XI

12. The methods of Groups V-VIII and X-XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the methods of Groups V-VIII and X-XI comprise different steps, may use different products and produce different results.

13. As set forth in MPEP § 803, the criteria for a proper restriction between patentably distinct inventions requires that the inventions must be independent or distinct as claimed, and a search of all the inventions would impose a serious burden on the examiner. Groups I-XI have been shown to be independent or distinct, for the reasons set forth above. MPEP § 803 also indicates that a serious burden on the examiner may be prima facie shown if the Examiner shows by appropriate explanation either separate classification, separate status in the art, or a different field of search. The inventions of Groups I-XI have acquired a separate status in the art because of their recognized divergent subject matter, as shown by their different classification. In addition, a search of all the inventions would require at a minimum a separate patented/non-patented literature search, a sequence search, and a class/subclass search, therefore a comprehensive examination of all groups would impose an undue burden on the Examiner. Thus, restriction for examination purposes as indicated is proper.

14. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

15. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and

process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

16. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement can be traversed (37 CFR 1.143).

17. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

18. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PMR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Delia M. Ramirez whose telephone number is (571) 272-0938. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy can be reached on (571) 272-0928. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Delia M. Ramirez, Ph.D.
Patent Examiner
Art Unit 1652

DR
July 21, 2005

NEW CENTRAL FAX NUMBER

Effective July 15, 2005

On July 15, 2005, the Central FAX Number will change to **571-273-8300**. This new Central FAX Number is the result of relocating the Central FAX server to the Office's Alexandria, Virginia campus.

Most facsimile-transmitted patent application related correspondence is required to be sent to the Central FAX Number. To give customers time to adjust to the new Central FAX Number, faxes sent to the old number (703-872-9306) will be routed to the new number until September 15, 2005. After September 15, 2005, the old number will no longer be in service and **571-273-8300** will be the only facsimile number recognized for "centralized delivery".

CENTRALIZED DELIVERY POLICY: For patent related correspondence, hand carry deliveries must be made to the Customer Service Window (now located at the Randolph Building, 401 Dulany Street, Alexandria, VA 22314), and facsimile transmissions must be sent to the Central FAX number, unless an exception applies. For example, if the examiner has rejected claims in a regular U.S. patent application, and the reply to the examiner's Office action is desired to be transmitted by facsimile rather than mailed, the reply must be sent to the Central FAX Number.